

Date: February 11, 2004 Label No. EV369584313US I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "Express Mail-Post Office to Addressee" service.

Stephanie Hill  
Name (Print)

  
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: KISHI et al.	)	Examiner: Unassigned
	)	
Application No.: Unassigned	)	Group Art Unit: Unassigned
	)	
Filed: February 11, 2004	)	Confirmation No.: Unassigned
	)	
Docket No.: 3190-011-01	)	Customer No.: 33432

For: METHOD FOR ASSAYING BIOLOGICAL SAMPLE COMPONENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

February 11, 2004

**INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 CFR 1.97(b)**

Sir:

The attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached Form PTO-1449. Documents were cited in parent Application No. 09/914,552 filed August 30, 2001. In accordance with M.P.E.P. §609, it is not necessary to provide copies of those documents with this filing.

This Information Disclosure Statement is being submitted before expiration of the three-month period following filing of the above-captioned application.

The above information is presented so that the Patent and Trademark Office can, in the first instance, determine any materiality thereof to the claimed invention. See 37 CFR 1.104(a) and 1.106(b) concerning the PTO duty to consider and use any such information. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the documents cited in the attached Form PTO-1449 be made of record therein and appear

Information Disclosure Statement  
U.S. Patent Application No. Unassigned

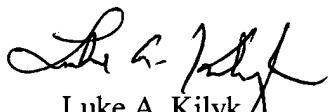
on the first page of any patent to issue therefrom.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in this application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

It is believed that no fee is required to make this a complete and timely filing. However, if it is determined that a petition or fee is required, the Commissioner is hereby authorized to charge any fee associated with this statement to our Deposit Account No. 50-0925 and please consider this a petition.

Respectfully submitted,



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Atty. Docket No.: 3190-011-01  
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FORM PTO-1449 (REV 7-80)		Atty. Docket No. 3190-011-01		Application No. Unassigned	
<b>INFORMATION DISCLOSURE STATEMENT</b>		APPLICANT: KISHI et al.			
		Filing Date: February 11, 2004		Group Art Unit: Unassigned	

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE, IF APPROPRIATE
		4,892,816	01/09/90	Akiba et al.	435	11	
		5,814,472	09/29/98	Miki et al.	435	11	
		4,892,815	1/1990	Kersher et al.	435	7	
		5,925,534	7/1999	Miki et al.	435	11	
		6,057,118	5/2000	Nakamura et al.	435	11	
		6,114,134	9/2000	Kishi et al.	435	11	

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES                  NO
		EP 0887422	12/30/98	Europe			
		EP 0913484	05/06/99	Europe			
		EP 1020532	07/19/00	Europe			
		WO 97/45553	12/04/97	WIPO			X Abstract
		WO 98/59068	12/30/98	WIPO			X Abstract
		11-56395	3/2/99	Japan			Abstract
		10-311833	11/24/98	Japan			Abstract
		09-000299	1/7/97	Japan			Abstract

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Supplementary Partial European Search Report dated June 27, 2002
	Gedik N. Direct Measurement of HDL Cholesterol in Serum... Biyokimya Dergisi 23(1)10-17, March 1998
	Yamauchi K. Evaluation of Reactivity Using Direct Assay Methods for HDL Lipoprotein Cholesterol. Rinsho Kagaku 1197. 26(3) 150-156
	Sugiuchi H. Homogeneous Assay for Measuring LDL Cholesterol... Clinical Chemistry 44(3)522-531, 1998
	Copy of International Preliminary Examination Report dated December 21, 2001

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.